Remarks

Claims 1-5 are pending in this application. Claims 4 and 5 have been withdrawn from consideration. Claims 1-3 have been amended in various particulars as indicated hereinabove.

Claims 1-3 were rejected under 35 U.S.C. 112, second paragraph.

Applicants believe that the claims as amended are now in compliance with 35 U.S.C. 112, second paragraph. In particular, it has been clarified that the medicament comprises one or more homeopathic dilutions. Illustrative Example 1 in the specification discloses three homeopathic dilutions used in a treatment regimen. Illustrative Example 2 in the specification describes three homeopathic dilutions administered to a patient. Illustrative Example 3 describes a medicament comprising one homeopathic dilution administered to a patient. Example 4 describes three homeopathic dilutions administered to a patient.

With regard to the terms "homeopathic dilutions of the potentiated…antibodies" now present in the Claims, Applicants provide the following explanation. The Patent Office is asked to refer to the report on "Q&A about Homeopathy", issued by the National Center for Complementary and Alternative Medicine of the National Institute of Health (NIH) (copy enclosed). On page 2 of the enclosed copy, the NIH report explains (emphasis added):

"In the late 1700s, Samuel Hahnemann, a physician, chemist, and linguist in Germany, proposed a new approach to treating illness."

"Hahnemann added two additional elements to homeopathy:

- A concept that became **"potentization,"** which holds that systematically diluting a substance, with vigorous shaking at each step of dilution, makes the remedy more, not less, effective by extracting the vital essence of the substance. If dilution continues to a point where the substance's molecules are gone, homeopathy holds that the "memory" of them--that is, the effects they exerted on the surrounding water molecules--may still be therapeutic.

- A concept that treatment should be selected based upon a total picture of an individual and his symptoms, not solely upon symptoms of a disease. Homeopaths evaluate not only a person's physical symptoms but her emotions, mental states, lifestyle, nutrition, and other aspects. In

> homeopathy, different people with the same symptoms may receive different homeopathic remedies.
>
> Hans Burch Gram, a Boston-born doctor, studied homeopathy in Europe and introduced it into the United States in 1825. European immigrants trained in homeopathy also made the treatment increasingly available in America. In 1835, the first homeopathic medical college was established in Allentown, Pennsylvania. By the turn of the 20th century, 8 percent of all American medical practitioners were homeopaths, and there were 20 homeopathic medical colleges and more than 100 homeopathic hospitals in the United States. "

As follows from the above, the concept of potentization as extreme dilution and that a remedy is prepared by extremely diluting the substance in a series of steps has been known and well defined in the US since at least the first half of the 19th century. Homeopathy asserts that this process can maintain a substance's healing properties regardless of how many times it has been diluted. Many homeopathic remedies are so highly diluted that not one molecule of the original natural substance remains in the dilution. Potentiated diluted remedy is believed (without being committed to any specific scientific theory) to have modified properties of the solvent molecules or the clusters of the solvent molecules to cause therapeutic effect. While no definite scientific theory exists to explain how potentiated remedies work, it has been known that they work, along with the well known term "potentiated", defining such remedies. Please refer to the Rule 132 Declaration of inventor Oleg Epshtein providing additional experimental data on the efficacy of the claimed medicament and the research behind those data. The introduced Claim amendments are also supported by paragraphs [0007] and [0015] and [0017] of the specification as published.

The present amended Claims now also refer to "one or more homeopathic dilutions of the potentiated polyclonal or monoclonal antibodies to the NO synthase being obtained according to homeopathic technology". Homeopathic dilutions and homeopathic technology have been known in the field of homeopathy in the US to anyone of average skill in that field for almost 200 years, as written in the referenced NIH report. Paragraph [0014] of the specification as originally filed describes the homeopathic potentiation technology of producing homeopathic dilutions (decimal dilutions and centesimal dilutions, as well as simultaneous shaking). Additionally, enclosed with this response is a PDF file is a copy of the English language translation of the German Homeopathic Pharmacopoeia (1978, British Homeopathic Association, 5th Supplement of 1991), which

has extensive description of the potentization technique and various types of homeopathic dilutions. Applicants believe that the proposed amendments alternatively define the claimed invention in a precise and definite manner.

Claims 1-3 were rejected under 35 U.S.C. 103(a) over Sinha (US Patent No. 6,379,669) in view of Davenas *et al.* Epshtein *et al.*, and Feldman *et al.* (US Patent No. 5,741,488). This rejection is respectfully traversed for the following reasons.

For an obviousness rejection to be proper, the Patent Office must meet the burden of establishing a prima facie case of obviousness. The Patent Office must meet the burden of establishing that all elements of the invention are disclosed in the cited publications, which must have a suggestion, teaching or motivation for one of ordinary skill in the art to modify a reference or combined references.[1] The cited publications should explicitly provide a reasonable expectation of success, determined from the position of one of ordinary skill in the art at the time the invention was made.[2]

Applicants assert that the Sinha patent contains no disclosure of one or more homeopathic dilutions of potentiated form of monoclonal, polyclonal, or natural antibodies to a prostate specific antigen (PSA), wherein one or more of the homeopathic dilutions of the potentiated form of antibodies to the prostate specific antigen being obtained by a homeopathic potentiation technology. The degrees of dilution in the Sinha patent are not homeopathic dilutions. The fact that Sinha talks about antibodies to the PSA does not make that patent contain a disclosure of the homeopathic dilution of the potentiated form of the antibodies, as explained in detail above and claimed in amended Claim 1.

The Feldman patent considers lowering the dosage of the antibodies in order to make the cheaper. That patent had no disclosure of the homeopathic dilutions (homeopathic doses) of the potentiated antibodies prepared by homeopathic technology. The degrees of dilution in Feldman are not homeopathic dilutions (not decimal or

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1 In re Lee, 277 F.3d 1338, 61 U.S.P.Q.2d 1430 (Fed. Cir. 2002).
2 In re Fine, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988); In re Wilson, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970); Amgen v. Chugai Pharmaceuticals Co., 18 U.S.P.Q.2d, 1016, 1023 (Fed. Cir. 1996).

centesimal dilutions), so no teaching or suggestion or motivation to use homeopathic dilutions of potentiated form of antibodies could be found in that patent.

In the cited Epshtein article there is no disclosure of the potentiated form antibodies to the specific antigen – PSA – and no disclosure in that article that teaches or suggests a medicament based on any kinds of antibodies at all. The fact that the Davenas and Epshtein articles might talk about biological activity without anything more specific does not means that the disclose the specific biological activity claimed in the present amended claims (effective in treating a prostate disease), as well as a specific antigen on which one or more homeopathic solutions of the potentiated form of antibodies can successfully act.

Furthermore, none of the cited publications discloses a medicament effective for treating prostate disease and comprised of homeopathic dilutions as claimed in amended independent Claim 1 . To further support this aspect of the invention, Applicants enclose additional evidence of efficacy of the claimed medicament in the form of an enclosed Declaration of inventor Oleg Epshtein under 37 CFR 132. Applicants also assert that the non-obviousness of the claimed invention is additionally supported by the data of solid commercial success, as reflected in the enclosed Declaration of inventor Oleg Epshtein under 37 CFR 132. Therefore, Applicants respectfully assert that amended independent Claim 1 and its dependent Claims comply with the requirements of 35 U.S.C. 103(a) and are patentable over the cited publications.

It is believed that the present application is in condition for allowance. A Notice of Allowance is respectfully solicited. Should any questions arise, the Examiner is encouraged to contact the undersigned.

Respectfully submitted,

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